

## **REMARKS**

The Office Action alleges that the present application contains two groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1 as follows:

Group I, claims 1-18, drawn to a method of treatment or prophylaxis of a various claimed conditions.

Group II, claim(s) 19, drawn to the compound of formula I.

The Office Action also alleges that the species are deemed to lack unity of invention, and that they are not so linked as to form a single general inventive concept under PCT Rule 13.1. According to the Office Action, the species are as follows:

Species of the Conditions;

1. NF $\kappa$ B related or associated condition
2. PKC $\beta$  related or associated condition
3. Vascular or immunological conditions, such as diabetes, inflammation, neurological conditions, cardiovascular disease and pain.

Species for the compound: definitions of R2, R4 and R6.

The Office Action has requested that applicant elect a single group for continued examination herein. In addition, applicant is requested to elect a single species for the condition being treated and to elect a compound to treat the specific condition or a specific compound of Formula I. In addition, applicant is to identify the claims readable on the elected species.

In order to be responsive to the Restriction Requirement, applicant provisionally elects, with traverse, the subject matter of Group I, that is, claims 1-18 for continued examination. Further, to be responsive to the election of species, applicant provisionally elects,

with traverse, vascular or immunological disorders, and in particular, cardiovascular disease. In addition, applicant provisionally elects the compound, with traverse,  $\beta$ -oxa-23:4n-6 (MP3), which is the first compound in the left hand column on page 28 of the instant specification.

Claims 1-6, 12 and 18 read on the elected species.

Applicant reserves the right to file one or more divisional applications directed to the non-elected subject matter. However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression 'technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

The Office Action alleges that Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. In support of the restriction requirement, the Office Action alleges that Groups I and II lack unity of invention because these groups require the technical feature of the compound of Formula (I), which, according to the Office Action, is not a special technical feature, providing the rationale that species of Formula (I) are disclosed in WO

96/11908 in Fig. 1h- Fig. 20. The Office Action concludes that Groups I and II are not so linked as to form a single general inventive concept and lack unity of invention.

Applicants respectfully submit that unity of invention is the issue at hand. Not anticipation. Applicants should be given the opportunity to argue patentability on the merits during prosecution with respect to the teachings of WO 96/11908. Restriction of the claims at this stage would deny Applicants such an opportunity.

Moreover, Applicant respectfully submits that the claimed subject matter is linked to form a single general inventive concept. Both Groups I and II relate to the compound of Formula I. More specifically, Group I relates to the use of the compound of Formula I and Group II relates to the compound of Formula I. Inasmuch as both groups recite a compound of Formula I, Groups I and II are related to form a single general inventive concept. Consequently, for the reasons provided, there is unity of invention. Thus, the restriction requirement between the groups should be withdrawn.

Additionally, Applicant respectfully submits that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups, one from the other, as presented by the Examiner.

Further, with respect to the species election, if used to restrict the subject matter of Group I, either by the scope of the compounds used or the specific use, it is respectfully submitted that the Office Action has not met its burden of establishing lack of unity of invention. It is well settled case law that the USPTO has the burden to show that the claims contain patentably distinct species. With respect to the compounds and with respect to the utility, the Office Action merely concludes that they lack unity of invention. The statement that the species are not so linked so as to form a general inventive concept is merely conclusionary. The Office

Action provides no rationale to support its allegation respecting the lack of unity with respect to the compound or the condition being used. The Office Action makes no showing in support thereof. Thus, with respect to the species election, it is respectfully submitted that the burden has not shifted to the applicant. Therefore, inasmuch as the Office Action has not met its burden, the election of species requirement should be withdrawn.

It is vital to all applicants that restriction and species election requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. § 121, which states that a patent issuing on a parent application “shall not be used as a reference” against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that 35 U.S.C. § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology, Inc. v. Lectra Systems, Inc., 916 F.2d 683, 16 U.S.P.Q.2d 1436 (Fed. Cir. 1990), that court held that § 121 does not insulate a patentee from an allegation of “obviousness-type” double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement and a species election requirement with inadequate authority can lead to situations in which an

applicant's legitimate patent rights are exposed to uncertainty and even extinguished.

Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, applicant respectfully urges the Examiner not to require restriction between the groups and between the species in cases such as the present application wherein various aspects of a unitary invention are claimed.

In addition, the Courts have recognized the advantages to the public interest to permit patentees to claim all aspects of their invention, as the applicant has done herein, so as to encourage the patentees to make a more detailed disclosure of all aspects of their invention. The C.C.P.A. has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. 112 all aspects of what they regard as their invention, regardless of the number of statutory classes involved. (Emphasis added).

In re Kuehl, 475 F.2d 658, 666, 177 USPQ 250, 256 (C.C.P.A. 1973).

Furthermore, Applicant respectfully requests that in view of increased Official Fees and the potential limitation of Applicant's financial resources, a practice which arbitrarily imposes a Restriction Requirement and a species election requirement may become prohibitive, and thereby contravenes the constitutional intent to promote and encourage the progress of science and the useful arts.

In view of the foregoing, it is respectfully urged that the Examiner reconsider and withdraw the requirements for restriction and election of species, and provide an action on the merits with respect to all of the subject matter in the pending claims.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Mark J. Cohen". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Mark J. Cohen

Registration No. 32,211

SCULLY, SCOTT, MURPHY & PRESSER, P.C.  
400 Garden City Plaza, Suite 300  
Garden City, New York 11530  
516-742-4343 - Telephone  
516-742-4366 - Fax

MJC/ech